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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO.            | CONFIRMATION NO. |
|---|-------------|------------------------|--------------------------------|------------------|
| 10/792,178  | 03/03/2004  | David E. Francischelli | P-8575.06                      | 4900             |
| 27581   | 7590        | 02/27/2006             |                                |                  |
| MEDTRONIC, INC.<br>710 MEDTRONIC PARK<br>MINNEAPOLIS, MN 55432-9924 |             |                        | EXAMINER<br>VRETTAKOS, PETER J |                  |
|   |             |                        | ART UNIT<br>3739               | PAPER NUMBER     |

DATE MAILED: 02/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|                              |                                |                                      |  |
|------------------------------|--------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | Application No.<br>10/792,178  | Applicant(s)<br>FRANCISCHELLI ET AL. |  |
|                              | Examiner<br>Peter J. Vrettakos | Art Unit<br>3739                     |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 March 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 34-61 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB08)<br>Paper No(s)/Mail Date <u>3-3-04</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The application is published application number: 2004/018 6465. The publication is classified in US 606/34.

The Applicant is requested to provide (or check for accuracy) at the beginning of the Specification updated status information (serial numbers and patent numbers) of all related applications. The effective filing date of this application is 4-27-00.

Pending claims as of 2-16-06 are 1-61.

Elected (traversed) claims 25-33 are examined below.

Non-elected / withdrawn claims are 1-24 and 34-61.

### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 3-3-04 is being considered by the examiner.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24, drawn to ablation apparatus, classified in class 606, subclass 41.
- II. Claims 25-33, drawn to method of ablation, classified in class 128, subclass 898.

III. Claims 34-61, drawn to an ablation system, classified in class 606, subclass 34.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I,III are **related as process and apparatus for its practice**.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus can be used to practice another and materially different process such as ablation of non-organic tissue as seen in Cates et al. (5,194,723).

Inventions III and I are related as **combination and subcombination**.

Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the system is sufficiently claimed to permit apprehensions of ablation of non-organic tissue. The subcombination has separate utility from ablation (therapy) such as imaging or mapping (diagnosis).

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their **different classification**, restriction for examination purposes as indicated is proper.

**During a telephone conversation** with Jeff Hohenshell on 2-15-06 a provisional election was made with traverse to prosecute the invention of group II, claims 25-33. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-24 and 34-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Drawings***

The drawings are objected to because figures 7 and 8 misspell "too" at least once (see box 717). The Applicant is requested to check the spelling in all figures. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version

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of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The claims are most consistent with the embodiment in figure 7.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 25-30 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Altshuler et al. (6,015,404).

Note: specific references in the patented disclosure below are not limiting to those excerpts. (The Office reserves the right in future actions to apply other excerpts, need be, from the patent.)

25. A method of ablating organic tissue, comprising: positioning a conductive element (16) adjacent the organic tissue; supplying power to the conductive element; sensing with a sensor (30) positioned adjacent the conductive element the vibration (col. 4:51-58) of the organic tissue; and reducing power to the conductive element when the vibration reaches a given value (42; col. 5:15-20).

26. The method of claim 25, further comprising: halting the power when the vibration reaches a given value (col. 5:15-20).

27. The method of claim 25, further comprising: supplying fluid from a fluid supply to the tissue; and halting the fluid supply when the vibration reaches a given value. See col. 6:6-12.

28. The method of claim 25 further comprising: sending a signal (36, col. 5:2-4; col. 5:26-27) from the sensor (30) to a switch (42) to reduce the power (col. 5:26-29).

29. The method of claim 25, further comprising: providing output (col. 5:15-17; col. 15:43-49) from an output device (46) when the vibration reaches a given value.

30. The method of claim 29 further comprising: sending a signal (36 or 88 in col. 7:17-18) from the sensor (30) to the output device (46); and sending an indicator signal from the output device.

33. The method of claim 25 wherein the sensor (30) is integrated (through 18) with the conductive element (16). See figure 1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Altshuler in view of Vesely et al. (6,246,898).



No piezoelectric sensors are expressly taught in Altshuler. (Although acoustic sensors are very often piezoelectric.)

However, in an analogous ablation (light and RF energy examples in col. 29:32-34 and claim 5, respectively) method, Vesely discloses piezoelectric sensors made of crystal (col. 1:49-50) or polymer (col. 21:31-34).

The combination of the two patents suggests acoustic feedback control of ablation using piezoelectric sensors. The motivation to combine the patents is fivefold (five reasons to use the sensing system of Vesely) and discussed in Vesely col. 1:61 through col. 2:42.

Therefore, at the time of the invention in would have been obvious to one of ordinary skill in the art to modify Altshuler in view of Vesely et al. by using the piezoelectric sensing means in Vesely in the Altshuler device and method. Again, the motivation to combine the patents is fivefold and discussed in Vesely col. 1:61 through col. 2:42.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Jahns et al. (6,887,238 ; 6,558,382), Cates et al. (5,194,723) – ablation feedback control with a piezoelectric sensor of non-organic tissue.

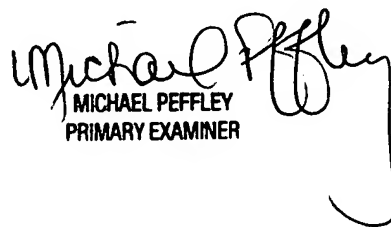
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Vrettakos whose telephone number is 571-272-4775. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pete Vrettakos  
February 19, 2006



MICHAEL PEFFLEY  
PRIMARY EXAMINER